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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,352	03/21/2001	Luis Lopez-Molina	2312-109	3472
6449	7590	12/13/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,352

Applicant(s)

LOPEZ-MOLINA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-29 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Applicant's submission filed on September 22, 2004 has been entered.

Claims 1-24 and 30-37 are cancelled.

Claims 25-29 and 38-44 are currently amended.

Claims 25-29 and 38-44 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25, and claims 28 and 29 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 25 as amended is directed to a transgenic seed, seedling or plant comprising a polynucleotide which comprises a heterologous promoter operatively linked to a nucleic acid encoding ABI5. The limitation "heterologous promoter" does not find support in the specification as originally filed and thus constitutes new matter.

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The Examiner acknowledges Applicants' assertion at page 5 of the reply that support for "heterologous promoter" can be found at page 15, lines 10-14, in the example of one constitutive promoter, and at page 17, lines 19-20, which refers to references describing heterologous inducible promoters. The Examiner disagrees, however, that the specification supports language directed to the use of any promoter other than the native ABI5 promoter. Reference to a single constitutive promoter at page 15, and the discussion of the use of activatable promoters at page 17, does not support the use of the broad term "heterologous promoter" in the claims, because constitutive and activatable promoters are each but a small and discrete subset of the broad genus of heterologous promoters which encompasses any promoter other than the native ABI5 promoter.

Claim Rejections - 35 USC § 103

Claim 26, 39 and 40 remain rejected, and claims 25, 28 and 29 are rejected, under 35 U.S.C. 103(a) as being unpatentable over either of Finkelstein R. et al. (The *Arabidopsis* abscisic acid response gene ABI5 encodes a basic leucine zipper transcription factor. Plant Cell. 2000 Apr;12(4):599-609) or Lopez-Molina L. et al. (A null mutation in a bZIP factor confers ABA-insensitivity in *Arabidopsis thaliana*. Plant Cell Physiol. 2000 May;41(5):541-7) in view of Kay et al. (Science, 5 June 1987, Vol. 236, No. 4806, pages 1299-1302), for the reasons of record set forth in the office action mailed June 24, 2004.

Applicants' arguments filed September 22, 2004, have been fully considered but they are not persuasive.

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Applicants argue that the first alleged motivation (that a skilled artisan would have combined the 355 promoter with the ABI5 coding sequence in order to produce the ABI protein in a quantity sufficient to characterize it) is not set forth in any of the prior art cited by the Examiner. Applicants submit that if it was desired to produce the protein in a quantity to characterize the protein, a skilled artisan would not have used plants to produce the desired quantities of protein. Applicants also argue that the second alleged motivation (that a skilled artisan would have combined the 355 promoter with the ABI5 coding sequence in order to determine the biological role of the ABI5 protein) is not set forth in any of the prior art references. Applicants submit that as a result of previous studies and the identification of ABI5 mutants, a biological role for the ABI5 protein was known and described in the primary references. Applicants further submit that transgenic plants of the primary references containing the native promoter operatively linked to the ABI5 coding sequence were prepared to confirm that the mutant phenotype was due to the mutant gene and to confirm the location of the gene for cloning and analysis. Applicants therefore argue that there is no motivation in either of the primary references to combine the 355 promoter with the ABI5 coding sequence to study the biological role of the ABI5 protein in planta. (reply page 7)

In response to Applicants' argument that there is no suggestion in the references to make a seed, seedling or plant comprising a polynucleotide comprising a constitutive promoter operatively linked to a nucleic acid sequence encoding ABI5 in order to produce the ABI5 protein, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the

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knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is some teaching, suggestion, or motivation to do so found in the knowledge generally available to one of ordinary skill in the art, as the use of transgenic plants and plant cells for the production of recombinant proteins was both well known to, and well within the abilities of, one of ordinary skill in the art at the time of Applicant's invention.

In response to Applicants' argument that there is no suggestion in the references to make a seed, seedling or plant comprising a polynucleotide comprising a constitutive promoter operatively linked to a nucleic acid sequence encoding ABI5 in order to determine the biological role of the ABI5 protein, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is some teaching, suggestion, or motivation to do so found in the knowledge generally available to one of ordinary skill in the art, as the use of gain of function analysis to characterize the function the of wild-type proteins encoded by genes initially mapped to mutant genetic loci was both well known to, and well within the abilities of, one of ordinary skill in the art at the time of Applicant's invention.

Applicants additionally argue that the prior art does not in fact contain any motivation to make the precise combination and arrangement of elements that is recited in the present claims,

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and "[t]o draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction -- an illogical and inappropriate process by which to determine patentability." *Sensonics, Inc. v. Aerosonic Corp.*, 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996); see also *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 30 U.S.P.Q. 2d 1377, 1380 (Fed. Cir. 1993). Applicants submit that since there is no motivation to combine the references, the Examiner's argument in this rejection, at best, amounts to an "obvious to try" analysis, which is not the standard under 35 U.S.C. §103. *In re O'Farrell*, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988). (reply pages 7-8)

In response to Applicants' argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claim 25, 27-29, 38 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Finkelstein R. et al. (The *Arabidopsis* abscisic acid response gene ABI5 encodes a basic leucine zipper transcription factor. *Plant Cell*. 2000 Apr;12(4):599-609) or Lopez-Molina L. et al. (A null mutation in a bZIP factor confers ABA-insensitivity in *Arabidopsis thaliana*. *Plant Cell Physiol*. 2000 May;41(5):541-7) in view of Gatz C. et al. (Stringent repression and

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homogeneous de-repression by tetracycline of a modified CaMV 35S promoter in intact transgenic tobacco plants. *Plant J.* 1992 May;2(3):397-404).

The claims are drawn to a transgenic seed, seedling or plant comprising a polynucleotide which comprises a heterologous inducible or derepressible promoter operatively linked to a nucleic acid sequence encoding abscisic acid insensitive 5 (ABI5), including a transgenic seed, seedling or plant that overproduces ABI5 in comparison to a nontransgenic plant, and a transgenic seed, seedling or plant that is hypersensitive to abscisic acid in comparison to a nontransgenic plant.

Finkelstein et al. teach transgenic *Arabidopsis* plants comprising a polynucleotide which comprises a native promoter operatively linked to a nucleic acid sequence encoding the protein encoded by the abscisic acid insensitive 5 locus of *Arabidopsis* (page 600 column 2 second full paragraph; page 601 Table 1). The transgenic plants taught by Finkelstein et al. overproduce ABI5 relative to the nontransformed *abi5* mutant plants, as mutant complementation was observed (page 605 Table 1). The transgenic plants taught by Finkelstein et al. are additionally hypersensitive to abscisic acid relative to the nontransformed *abi5* mutant plants (page 605 Table 1). Finkelstein et al. also teach that abscisic acid (ABA) regulates many agronomically important aspects of seed development, including synthesis of storage proteins and lipids and acquisition of desiccation tolerance and dormancy and that vegetative responses to ABA include induction of stomatal closure and tolerance of drought, salt, and cold stresses (page 599 column 1 first paragraph).

Lopez-Molina et al. teach transgenic *Arabidopsis* plants comprising a polynucleotide which comprises a native promoter operatively linked to a nucleic acid sequence encoding the

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protein encoded by the abscisic acid insensitive 5 locus of *Arabidopsis* (page 543 Table 1; page 545 column 1 first full paragraph). The transgenic plants taught by Lopez-Molina et al. overproduce ABI5 relative to the nontransformed *abi5* mutant plants, as mutant complementation was observed (page 543 Table 1). The transgenic plants taught by Lopez-Molina et al. are additionally hypersensitive to abscisic acid relative to the nontransformed *abi5* mutant plants (page 543 Table 1). Lopez-Molina et al. also teach that abscisic acid (ABA) maintains seed dormancy, prevents precocious germination, and mediates plant stress responses to drought, cold and osmotic imbalances (page 541 column 1 first paragraph).

Finkelstein et al. and Lopez-Molina et al. do not teach the use of a heterologous inducible or derepressible promoter.

Gatz C. et al. (Stringent repression and homogeneous de-repression by tetracycline of a modified CaMV 35S promoter in intact transgenic tobacco plants. *Plant J.* 1992 May;2(3):397-404) teach the use of a heterologous 'Triple-OP' promoter in transgenic tobacco plants that constitutively express a tet repressor protein which binds to tet operator sequences in the 'Triple-OP' promoter thus repressing its activity. The 'Triple-OP' promoter taught by Gatz C. et al. is both inducible and derepressible by tetracycline, which abolishes the DNA binding affinity of the tet repressor protein (page 398 Figure 1). Gatz C. et al. also teach that plant transformation technology in general is useful for modulating the expression of endogenous proteins in order to analyze and understand the contribution of a defined gene to an organism's phenotype, and that in this regard the use of a regulatable promoter such as the 'Triple-OP' promoter is often desirable in order to induce expression of the defined gene at defined time points during development, or only in certain parts of a transgenic plant (page 397 column 1).

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to transform plants with a polynucleotide comprising a heterologous inducible or derepressible promoter, such as the 'Triple-OP' promoter taught by Gatz C. et al., operatively linked to a nucleic acid sequence encoding ABI5, as taught by Finkelstein et al. and Lopez-Molina et al. One skilled in the art would have been generally motivated to express ABI5 from such a promoter in order to induce expression of ABI5 at defined time points during development, or only in certain parts of a transgenic plant, in order to analyze and understand the contribution of ABI5 to a plant's phenotype, as indicated by Gatz C. et al. One skilled in the art would have been specifically motivated to express ABI5 from such a promoter in order to induce expression of ABI5 at defined time points in order to analyze and understand the contribution of ABI5 to processes affected by ABA, such as the synthesis of storage proteins and lipids and the acquisition of desiccation tolerance and dormancy in seeds, or the induction of stomatal closure and drought, salt, and cold stress tolerance, as indicated by Finkelstein et al. and Lopez-Molina et al. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success given the success of Finkelstein et al. and Lopez-Molina et al. in making transgenic *Arabidopsis* plants that comprise and express a nucleic acid sequence encoding ABI5, and given the success of Gatz C. et al. in using the 'Triple-OP' promoter to obtain transgenic plants in which they could control the expression of a transgene.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

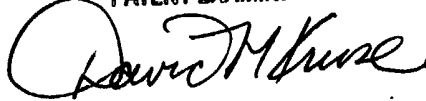
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
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DAVID H. KRUSE, PH.D.
PATENT EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written over a circular stamp or mark.

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